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Intellectual Property Law

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DATE: 23 October 2001

FROM: David H. Rogers, Ph.D.
Technical advisor
for Robin M. Silva

TO: Examiner Janet Andres

FAX NO.: (703) 308-0294

NUMBER OF PAGES (including this transmittal sheet):

(5)

If you do not receive clear copies of any pages, please let us know.

RE: U.S. Patent Application
Serial No. 09/404,010
Filing Date: 23 September 1999
For: *Novel TRAF4 Associated Cell Cycle Proteins, Compositions and Methods of Use*
Inventors: Ying Luo, et al.
Our File No.: A-68294/RMS/DHR

MESSAGE:

Dear Examiner Andres,

Following from our phone interview of 17 October 2001, please find attached a copy of a 132 declaration executed by Xiang Xu. Robin Silva will attempt to contact you tomorrow to discuss the declaration.

Very truly yours,

Dave Rogers.

IMPORTANT/CONFIDENTIAL: This facsimile communication is intended only for the use of the individual or entity to which it is addressed. The following pages contain information which may be privileged and/or confidential. If the reader of this facsimile is not the intended recipient, or the employee or agent responsible for delivering the facsimile to the intended recipient, you are hereby notified that any disclosure of the contents, or dissemination or distribution of this facsimile to others, or copying of this communication, is strictly prohibited. If you have received this communication in error, please telephone us immediately at (415) 781-1989 and return all copies of this facsimile to us by mail. We thank you for your cooperation.

PATENT
Attorney Docket No.: A-68294/RMS/DHR

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:) Examiner: Andres, J.
Luo et. al.)
Serial No.: 09/404,010) Group Art Unit: 1646
Filed: 23 September 1999)
For: *Novel TRAF4 Associated Cell Cycle Proteins, Compositions and Methods of Use*)

Ans. Inv. ✓

CERTIFICATE OF MAILING

I hereby certify that this correspondence, including listed enclosures, is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, DC 20231

on _____

Signed: _____
Todd V. Leone

DECLARATION PURSUANT TO 37 C.F.R. § 1.132

**Assistant Commissioner for Patents
Washington, DC 20231**

Sir:

I, Xiang Xu, Ph.D., do hereby declare as follows:

1. I am a Senior Scientist Project Leader at Rigel Pharmaceuticals, Inc., a biotechnology company located in San Francisco, CA, and I have been involved with the cell cycle program at Rigel for the past 4 years.

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2. I have read and understand the U.S. patent application Serial No. 09/404,010. I have also read and understand the Office Action dated 14 February 2001. I am familiar with the Examiner's position expressed therin that the instant specification does not enable one of reasonable skill in the art to make and use the claimed Mkinase compositions for a substantial, credible, and real world utility.

3. I disagree with the Examiner's position that the specification does not enable one of reasonable skill in the art to make and use the claimed Mkinase compositions for a substantial, credible, and real world utility.

4. The specification at page 4, lines 21-22, and page 5, lines 13-15, and page 31 lines 5-7, asserts a number of characteristics and functions for the cell cycle protein Mkinase which indicate that the claimed Mkinase compositions have utility. Specifically, the specification asserts that the Mkinase protein binds to the Trx4 protein, has homology to MAP kinases and cyclin-dependent kinases, and possesses an N-terminal kinase domain. The specification further asserts that Mkinase phosphorylates substrate proteins and modulates cell proliferation. Given these assertions, I would expect to be able to use the claimed Mkinase compositions for a substantial, credible, and real world utility. For example, I would expect to be able to use the claimed Mkinase compositions in screening assays for identifying bioactive agents capable of modulating Mkinase activity, as set forth in one embodiment at page 31, lines 2-7 of the instant specification.

5. Attached hereto are the results of experiments performed at Rigel Pharmaceuticals, Inc., which demonstrate that my expectations from reading the application are confirmed as accurate. Specifically, attached Appendix A shows that Mkinase phosphorylates the MAP kinase substrate myelin basic protein (MBP) in vitro. These results support the assertions set forth in the instant application that the cell cycle protein Mkinase has homology

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to MAPK, possesses an N-terminus kinase domain, and phosphorylates substrate proteins which include MAPK substrate proteins.

6. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that the making of willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardized the validity of the application or any patent issuing thereon.

Date: Oct. 22. 01

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